**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OHIO**

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES DISTRICT COUNCIL 37 HEALTH & SECURITY PLAN, individually and on behalf of all those similarly situated,

Plaintiff,

-against-

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS, LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; INSYS THERAPEUTICS INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; and MCKESSON CORPORATION,

Defendants.

Case No. 1:17-cv-2585

**CLASS ACTION COMPLAINT AND JURY TRIAL DEMANDED**

Plaintiff, AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, DISTRICT COUNCIL 37 HEALTH & SECURITY PLAN ("DC 37"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Mallinckrodt Plc, Mallinckrodt LLC, Allergan PLC f/k/a Actavis PLS, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC, Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., Insys Therapeutics, Inc., ("Manufacturer Defendants"), AmerisourceBergen Drug Corporation; Cardinal Health, Inc., and McKesson Corporation ("Distributor Defendants") (collectively "Defendants"). At all relevant times, Plaintiff has paid and/or provided reimbursement for some or the entire purchase price on behalf of its members for prescription opioid's which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants during the Class Period. Plaintiff has sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein. Based upon personal knowledge, information, belief, and investigation of counsel, DC 37 specifically alleges:

## INTRODUCTION

1. Opioids are estimated to kill upwards of 100 Americans per day, and cost health services providers billions of dollars per year both in payments for unnecessary and harmful prescriptions of the drugs themselves, and the costs of treating the diseases and injuries they cause.

2. Opioid manufacturing and distributing companies systematically and repeatedly disregarded the health and safety of their customers and the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

3. Corporate greed and callous indifference to known, serious potential for human suffering have caused this public health crisis. Defendants helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in this country.

4. For too long, the public at large has been forced to contend with the deadly aftermath of the proliferation of opioids in society. Those responsible should be required to internalize the costs with which they have burdened society.

5. Defendants' marketing — and not any medical breakthrough —rationalized prescribing opioids for chronic pain and opened the floodgates for opioid use and abuse.

6. Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no good evidence to support Defendants' claims.

7. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales

representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages.

8. Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

9. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.

10. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of

[whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[1]

11. This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale, and a population of patients physically and psychologically dependent on them. When those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

## JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. ("RICO").

13. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of Ohio, purposefully directed their actions toward Ohio, consensually submitted to the jurisdiction of Ohio when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Ohio necessary to constitutionally permit the Court to exercise jurisdiction.

14. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in this District.

[1] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, *available at* http://turnthetiderx.org/.

## PARTIES

### A. Plaintiff DC 37

15. American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan is a non-profit health, self-funded, and welfare benefit plan covering public sector employees, retirees and their families. Its principal place of business is in New York, New York. District Council 37 ("DC 37") is New York City's largest public employee union. DC 37's health and welfare benefit plan covers approximately 125,000 active union members as well as 50,000 retirees and their families—totaling over 300,000 lives. DC 37 includes 51 local unions, representing public sector employees serving in thousands of job titles from Accountants to Zoo Keepers. Members covered by DC 37's benefit plan work in almost every agency in New York City including but not limited to the City's police and fire departments, hospitals, schools, libraries, social service centers, water treatment facilities, and city colleges. DC 37 provides supplemental health benefits, including a prescription drug benefit to its members, retirees, and their families. Throughout the Class Period and throughout the United States, DC 37 indirectly purchased, paid, and reimbursed for opioids intended for consumption by its members, retirees, and their families. Given its plan members' past purchases of opioids, DC 37 anticipates that it will continue to purchase and/or provide reimbursement for opioids in the future.

### B. Manufacturer Defendants

#### 1. Purdue and Associated Companies

16. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. It is owned principally by parties and descendants of Mortimer and Raymond Sackler.

17. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

18. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

19. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company, Inc. (collectively, "Purdue Pharma") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids throughout the United States.

### 2. Cephalon and Associated Companies

20. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

21. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

22. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

23. Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Cephalon") are in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

### 3. Janssen and Associated Companies

24. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

25. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson.

26. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

27. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of Johnson & Johnson until July 2016. Noramco, Inc. is or had been part of Johnson & Johnson's opium processing by making active pharmaceutical ingredients ("APIs") for opioid painkillers.

28. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

29. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

30. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

31. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

#### 4. Endo and Associated Companies

32. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

33. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

34. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

35. Endo also is or has been in the business of manufacturing, selling, promoting, and/or distributing generic opioids through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

**5. Mallinckrodt and Associated Companies**

36. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri.

37. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, Plc. Mallinckrodt, Plc and Mallinckrodt, LLC (collectively, "Mallinckrodt") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids throughout the United States.

**6. Allergan and Associated Companies**

38. Defendant Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

39. Defendant Actavis Plc acquired Defendant Allergan Plc in March 2015, however the combined company changed its name to Allergan Plc in January 2013.

40. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then changed the name to Actavis Plc in October 2013.

41. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

42. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

43. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

44. Each of these defendants is owned by Defendant Allergan Plc, which uses them to market and sell its drugs in the United States.

45. Defendant Allergan Plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Allergan") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

**7. Insys**

46. Insys Therapeutics, Inc. ("Insys") is a Delaware company with its principal place of business in Chandler, Arizona. Insys is or has been in the business of manufacturing, selling, promoting, and/or distributing fentanyl-based cancer spray Subsys.

### C. Distributor Defendants

#### 1. AmerisourceBergen

47. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

48. According to its 2016 Annual Report, Amerisource is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."

#### 2. Cardinal Health

49. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal Health generated revenues of $121.5 billion.

50. Cardinal Health is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. Additionally, in December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal Health has, at all relevant times, distributed opioids nationwide.

#### 3. McKesson

51. Defendant McKesson Corporation ("McKesson") is a Delaware Corporation with its principal place of business located in San Francisco, California.

52. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America.

53. For fiscal year ended March 31, 2017, McKesson generated revenues of $198.5 Billion.

54. In its 2017 Annual Report, McKesson states that it "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively."

55. According to the 2017 Annual Report, McKesson "pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico."

56. McKesson is the largest pharmaceutical distributor in the United States.

57. McKesson has more than 40,000 customers nationally.

58. Collectively, McKesson, AmerisourceBergen, and Cardinal Health account for 85 percent of the drug shipments in the United States. These companies together collect about $400 billion in annual revenue.

**D. Defendants' Agents**

59. All of the actions described in this Class Action Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendant's affairs within the course and scope of their duties and employment, and/or with Defendant's actual, apparent, and/or ostensible authority.

## CONTINUING VIOLATIONS

60. This Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and

accumulating harm within the applicable statutes of limitations. Thus, DC 37 and the members of the Class can recover for damages that they suffered during any applicable limitations period.

## CLASS ACTION ALLEGATIONS

61. DC 37, on behalf of itself and all other similarly situated purchasers, seeks damages, trebled where available under applicable law, against Defendants based on allegations of the creation of a conspiracy and conduct of an illegal enterprise to expand the market for opioids.

62. This is a quintessential class action. The most significant questions of law and fact on which each Defendant's liability to the Class turns are common ones, because the knowledge, conduct and duty of each Defendant, and whether that duty was breached to the economic detriment of those who paid for the resulting avalanche of opioids, does not depend on the individual characteristics of the Class members, but on conduct directed by Defendants to patients and health care providers at large. Defendants saw an opportunity to make enormous profits by creating a market for opioids, and saturating that market with knowledge of, but without regard for, the economic consequences to anyone but themselves.

63. DC 37 brings this action on behalf of itself and as a class action under Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), seeking actual and treble damages, as well as equitable and injunctive relief, on behalf of a Class of purchasers (the "Class") defined as follows:

All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit providers, in the United States of America and its territories, who have, from the inception of Defendants' course of allegedly RICO- violative conduct as alleged herein, through a date to be established by the Court (such as the date of approval of class notice), paid or incurred costs for prescription opioids manufactured, marketed, sold, or distributed by the Defendants, for purposes other than resale.

This class excludes: (a) Defendants and their subsidiaries, affiliates, and controlled persons;

(b) Defendants' officers, directors, agents, servants, or employees of Defendants, and the immediate family members of any such person; (c) all persons who make a timely election to be excluded from the proposed Class; (d) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (e) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

64. While DC 37 does not know the exact number of the members of the Class, DC believes there are thousands of members in the Class. The Class members are so numerous and dispersed throughout the United States that joinder of all members is impracticable. The Class is composed of thousands of third-party payors, and the disposition of their claims in a Class action will benefit both the parties and the Court. Defendants sell millions of doses of opioids in the United States every year, and thus the Class is sufficiently numerous to make joinder impracticable. The Class members can be identified by, *inter alia,* records maintained by Defendants, pharmacies and pharmacy benefit managers ("PBMs").

65. Common questions of law and fact exist as to all members of the Class. This is particularly true given the nature of Defendants' schemes, which were spread across the country and directed at all Class members, thereby making appropriate relief with respect to the Class as a whole. Such questions of law and fact common to the Class include, but are not limited to:

a. Whether Defendants misrepresented the safety and efficacy of opioids, to the financial detriment of the Class;

b. Whether Defendants engaged in a conspiracy or conspiracies to promote the sales of opioids;

c. Whether Defendants engaged in a conspiracy or conspiracies to suppress adverse information about opioids;

d. Whether Defendants have made material misrepresentations of fact, or failed to state material facts regarding the addiction risks associated with opioids, which material misrepresentations or omissions operate as a fraud upon the Class;

e. Whether Plaintiff and the class paid for more opioids than for other efficacious drugs that were available at cheaper prices, and/or paid for more opioids due to addiction, and/or paid for treatment including drug addiction treatment, and emergency medical care including the costs of opioid overdose reversal drugs, such as Naloxone Hydrochloride (Narcan), as a result of the abuse, misuse, addiction and/or overdose of opioids.

f. Whether persons who took opioids are at increased risk of severe and permanent injuries, including misuse, addiction, and/or overdose;

g. Whether, in marketing and selling opioids, Defendants failed to disclose the dangers and risks to the health of persons ingesting the drug;

h. Whether Defendants failed to warn adequately of the adverse effects of opioids, including addiction and overdose;

i. Whether Defendants misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects, and convenience of opioids;

j. Whether Defendants knew or should have known that the ingestion of opioids leads to serious adverse health effects;

k. Whether Defendants adequately tested opioids prior to selling it;

l. Whether Defendants manufactured, marketed, distributed and sold opioids notwithstanding their knowledge of the drugs' dangerous nature;

m. Whether Defendants knowingly omitted, suppressed and/or concealed material facts about the unsafe and defective nature of opioids from government regulators, the medical community, third party payors, and/or the consuming public;

n. Whether the Class has been damaged, and if so, the extent of such damages and/or the nature of the equitable relief, statutory damages, or punitive damages to which the Class is entitled;

o. Whether Defendants were and are unjustly enriched by its acts and omissions, at the expense of the Class;

p. The amount of attorneys' fees, prejudgment interest, and costs of the suit to which the Class is entitled.

q. Whether Defendants engaged in conduct that violates federal RICO statutes in promoting the sales of and suppressing adverse information about opioids; and

r. Whether Defendants engaged in a conspiracy to promote the sales of and suppress adverse information about Opioids in violation of federal RICO statutes.

s. Whether Defendants unjustly enriched themselves to the detriment of DC 37 and the members of the Class;

t. Whether the conduct of Defendants, as alleged in this Complaint, caused injury to the business or property of DC 37 and the members of the Class;

66. The questions of law and fact common to the members of the Class predominate over any questions affecting only individual members.

67. DC 37's claims are typical of the claims of Class members. DC 37 and all members of the Class are similarly affected by Defendants' wrongful conduct in that they sustained damages arising out of the Defendants' wrongful conduct as detailed herein.

Specifically, Plaintiff, having expended substantial sums for the purchase of opioids and treatment for their abuse. DC 37's claims arise out of the same common course of conduct giving rise to the claims of the other members of the Class.

68. DC 37 will fairly and adequately protect the interests of the Class. DC 37 is a member of the Class, and DC 37's interests are coincident with, and not antagonistic to, those of the other members of the Class. DC 37 is represented by counsel who are competent and experienced in the prosecution of class action litigation.

69. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

70. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

## BACKGROUND

### A. The History of Opioids and Addiction

71. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, whose pain-relieving properties and dangerous qualities have been recognized for millennia.

72. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.[2]

73. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

74. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.[3]

75. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioids carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

76. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of

[2] Martin Booth, Opium: A History, 20 (Simon & Schuster Ltd. 1996).

[3] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol, No. 43 (2005).

complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

77. Opioids include brand-name drugs and generics like oxycodone and hydrocodone. They are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.

78. Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety.

79. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

80. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, and marketed opioids for the management of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

81. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. Two states are now pushing to use the drug's powerful properties to execute prisoners on death row.[4]

82. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[5]

83. The CDC estimates that approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.[6]

84. According to the CDC, opioids are responsible for the majority of drug overdoses today.[7] Additionally, opioid overdose have quadrupled nationally since 1999.[8]

85. The youngest members of society have also been affected by the opioid crisis. Eighty-seven children died of opioid intoxication in 2015, according to the Centers for Disease Control and Prevention, up from just 16 in 1999. Toddlers and young children are increasingly being found unconscious or dead after consuming an adult's drugs, and there has been a surge of opioid-dependent newborns.

86. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. Throughout this Complaint, "addiction" refers to the entire range of

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[4] William Wan & Mark Berman, *States to try new ways of executing prisoners. Their latest idea? Opioids.*, Wash. Post (Dec. 9, 2017), https://www.washingtonpost.com/national/health-science/states-choose-new-ways-to-execute-prisoners-their-latest-idea-opioids/2017/12/09/3eb9bafa-d539-11e7-95bf-df7c19270879_story.html?utm_term=.c37d8e3e76b3

[5] Rudd et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015, 65 Morbidity & Mortality Wkly. Rep. 1445, 1450 (2016).

[6] Heroin Overdose Data, Ctrs. For Disease Control & Prevention, https://www.cdc.gov/drugoverdose/data/heroin.html

[7] *Id.*

[8] Drug Overdose Death Data, Ctrs. For Disease Control & Prevention, https://www.cdc.gov/drugoverdose/data/statedeaths.html. Drug deaths take a long time to certify, so this is the most recent available data. https://www.cdc.gov/nchs/data/vsrr/report001.pdf

substance abuse disorders.[9] Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

**B. Prior Bad Acts**

87. Defendants have long known about the dangers of their opioid products, and the alarming quantities in which they were pouring into communities all across the country, because they have been sued, fined, and criminally convicted for failing to mitigate these problems.

88. For example, in 2007 Purdue settled criminal and civil charges against it for "misbranding" OxyContin. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly $635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.[10]

89. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[11] The DEA also published suggested questions that distributor should ask prior to shipping controlled substances, in order to know their customers.

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[9] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

[10] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[11] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Sept. 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Dec. 27, 2007); "Suggested Questions a Distributor should ask prior to Shipping Controlled Substances, *Deadiversion.usdoj.gov/*, U.S. Dept. of Justice, Drug Enforcement Administration; 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Rannazzisi May 5, 2015 Testimony.

90. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

91. In 2008, McKesson McKesson agreed to pay $13.3 million to settle the allegations and to strengthen its controls by implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids.

92. However, documents that have been recently unsealed show that five months after the 2008 settlement, the board's audit committee was notified of "serious deficiencies" in its system to spot suspicious opioid shipments. [12]

93. Inspections of some of McKesson's distribution facilities in 2013 found the company "did not fully implement or adhere to its own" compliance program. The findings forced McKesson to admit that it failed to report suspicious opioid shipments to the DEA and sign another settlement with DOJ that included tougher and verifiable compliance responsibilities, as well as a $150 million fine.

[12] Anders Melin & Jef Feeley, *McKesson Records Show Failed Opioid Oversight, Lawsuit Says*, Bloomberg (Dec. 8, 2017 10:34 A.M.), https://www.bloomberg.com/news/articles/2017-12-08/mckesson-investor-claims-board-failed-oversight-duty-on-opioids

94. In 2013, Cardinal paid a $34 million fine for failing to report suspicious orders of controlled substances.

95. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana,[13] the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA require "that Endo Pharmaceuticals remove [Opana ER] from the market." The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[14]

96. Two former CEOs of Insys have been charged in an indictment along with other former Insys executives and managers, who were initially charged in December 2016.[15] The indictment said that, beginning in 2012, Kapoor, Babich and others devised a scheme to pay speaker fees and other bribes to medical practitioners to prescribe Subsys and to defraud insurers into approving payment for it.

97. Federal charges have also been filed in several other states against other ex-Insys employees and medical practitioners who prescribed Subsys. Insys also faces lawsuits by attorneys general in Arizona and New Jersey. It previously paid $9.45 million to resolve investigations by attorneys general in Oregon, New Hampshire, Illinois and Massachusetts.

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[13]Press Release, State of Indiana Health Department, *available at* http://www.in.gov/activecalendar/EventList.aspx?view=EventDetails&eventidn=210259&information_id=211489&type=&syndicate=syndicate.

[14] CNN Wire, *FDA wants Opioid at Center of Scott County HIV Outbreak Pulled off Market,* Fox59.com (June 9, 2017 7:45 A.M.) http://fox59.com/2017/06/09/fda-wants-opioid-at-center-of-scott-county-hiv-outbreak-pulled-off-market/; Press Release, FDA Requests Removal of Opana ER for Risks Related to Abuse, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[15]*Billionaire Insys Founder to Plead Not Guilty in Opioid Bribery Case*, Reuters (Nov. 16, 2017), http://fortune.com/2017/11/16/insys-john-kapoor-opioid-case/.

98. In 2017, The Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[16]

**C. Opioid Crisis Today**

99. The epic scale of the crisis ravaging the country has gotten too big to ignore. What was once considered a problem only amongst the rural poor now touches every demographic group – including those with historically low rates of drug use.

100. The opioid epidemic is America's deadliest overdose crisis ever. The most recent CDC data, from 2015, show the opioid death toll exceeded 33,000 that year.

101. By comparison, more than 58,000 US soldiers died in the entire Vietnam War, nearly 55,000 Americans died of car crashes at the peak of such deaths in 1972, more than 43,000 died due to HIV/AIDS during that epidemic's peak in 1995, and nearly 40,000 died of guns during the peak of firearm deaths in 1993.[17]

102. Nevertheless, opioid sales overall totaled $8.6 billion and continue to rise, according to data from Quintiles IMS Holdings Inc.[18]

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[16] Press Release, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations, available at* https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[17] German Lopez, Drug overdose deaths skyrocketed in 2016, Vox (Sept. 5, 2017 12:10 P.M.), https://www.vox.com/policy-and-politics/2017/9/5/16255040/opioid-epidemic-overdose-death-2016.

[18] Esme Deprez and Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes On the Opioid Industry*, Bloomberg (Oct. 5, 2017), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry

**D. The Cost of Defendants' Scheme to Third Party Payors such as DC 37**

103. Starting in the 1990s, employee health plans have increasingly included prescription drug coverage. Thus, insurers have assumed an increasing share of prescription drug expenditures.

104. Prescription opioid drug spending grew dramatically from 1999 to 2012. Americans spent $2.3 billion on prescription opioids in 1999. By 2006, spending had almost tripled to more than $7.0 billion. Since 2006, expenditures have been relatively stable compared to this earlier increase, with total expenditures of $7.4 billion in 2012.[19]

105. Researchers at the National Center for Injury Prevention, part of the Centers for Disease Control (CDC) now believe that public and private insurers pay the majority of prescription drug costs for opioid pain relievers.[20]

106. Researchers used data from the Medical Expenditure Panel Survey (MEPS) to examine trends in opioid prescribing and expenditures by payer type. They found that consumer out-of-pocket spending on opioids per 100 morphine mg equivalents, a standard reference measure of strength for various opioids, declined from $4.40 in 2001 to 90 cents in 2012, with insurers paying an increasingly larger share of the cost.

107. Whereas in 1999, 53% of spending on opioid pain relievers was out-of-pocket, by 2012, out-of-pocket spending had declined to 18% of all expenditures.

108. The retrospective cohort study revealed that hospitalizations related to opioid abuse/dependence rose significantly from 301,707 in 2002 to 520,275 in 2012, an increase

[19] Tracey Walker, *New payer trends for opioids coincide with epidemic* , Managed Healthcare Executive (May 10, 2016), http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/new-payer-trends-opioids-coincide-epidemic.

[20] Chao Zhou, et al., *Payments For Opioids Shifted Substantially To Public And Private Insurers While Consumer Spending Declined*, 1999–2012, Health Affairs (Vol. 35, No. 5), *available at* https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2015.1103.

of 72%. Overall hospitalizations during the same time period remained largely consistent: slightly growing from 36.52 million to 36.48 million.[21]

109. The estimated total charge per hospitalization related to opioid abuse/dependence in 2012 was more than $28,000. For cases associated with an infection: $107,000 for hospitalizations.

110. One of the authors of the study, Dr. Matthew Ronan, a hospitalist and an instructor at Harvard Medical School, said injection opioid abuse leads to many complications—one of the most known is serious infection.

111. Opioid-related hospitalizations with serious infection jumped 91% to 6,535 over the ten year time period reviewed.

112. More than quadrupling between 2002 and 2012, total inpatient charges related to opioid abuse and dependence reached $14.85 billion in 2012. Approximately $700 million of that went to paying hospitalizations related to opioid-associated infections.

113. The study characterizes the sobering impact of opioid-related infections on healthcare systems, and on the patients themselves who are suffering from addiction.

114. Dr. Matthew Ronan also emphasized that, "Up to 5% of patients presenting to the hospital with an infection related to their opioid abuse will die during hospitalization. Of those that survive to hospital discharge, more than a quarter will be too functionally impaired to return home immediately and will need to spend time in a rehab or skilled nursing facility. These are sobering statistics in a patient population with an average age of 43 years."

[21] C.J. Arlotta, *How Opioid Abuse Contributes To Rising Healthcare Costs*, Forbes (May 3, 2016), https://www.forbes.com/sites/cjarlotta/2016/05/03/opioid-abuse-contributes-to-rising-health-care-costs/#7e36c30873a3.

115. In 2014, there were 18,893 deaths involving prescription opioids in 2014, up 16% from the previous year, according to the National Center for Health Statistics.

116. In 2016, traditional opioid painkillers, such as OxyContin and Percocet, were involved in about 14,400 overdose deaths and non-methadone synthetic opioids like fentanyl, were linked to more than 20,100 overdose deaths based on the preliminary figures from the National Center for Health Statistics.

**2. DC 37's Rising Costs of Treating Opioid Addiction**

117. DC 37's own experience treating opioids illustrates these national trends.

118. DC 37 has purchased (directly or indirectly), paid for, and reimbursed for opioids intended for consumption by its members, retirees, and their families.

119. DC 37's costs for treatment related to the misuse, addiction, and/or overdose of opioids have risen over the last decade.

120. Payments for emergency department visits for opioid misuse, addiction, and/or overdose have increased.

121. Payments for emergency department visits for infections related for opioid misuse, addiction, and/or overdose have increased.

122. Payments for hospitalizations related to the misuse, addiction, and/or overdose of opioids have increased.

123. Payments for medicines to treat HIV and/or hepatitis C related to the opioid misuse, addiction, and/or overdose have increased.

124. Payments for opioid overdose reversal medication such as Naloxone Hydrochloride (Narcan) have increased.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF
### RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO)
### 18 U.S.C. §1961 et. seq.

125. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

126. Plaintiff brings this Count against all Defendants.

127. Defendants are persons within the meaning of 18 U.S.C. §1961(3) who conducted the affairs of the enterprises described below through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

128. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. §1962(c).

### Relevant Enterprises

129. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The definition of "enterprise" in Section 1961(4) includes both legitimate and illegitimate enterprises.

130. Defendants engaged in two relevant illegal enterprises in violation of these statutes: the Opioid Promotion Enterprise and the Opioid Diversion Enterprise.

131. The Opioids Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOL's; as well as external and other as yet

unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioids Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Defendants to fraudulently market Opioids as scientifically proven as safe and effective. The Opioids Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioids Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to ensure the prescription opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioids Promotion Enterprise.

132. The Opioids Diversion Enterprise is an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiff and the Class suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

133. Members of the Opioid Diversion Enterprise, finding it impossible to legally achieve their ever-increasing sales ambitions, systematically and fraudulently violated their

statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

134. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

135. The Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

136. Each of the Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Defendants.

137. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

138. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the legal enterprise (HDA) were each used by the Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the "RICO Enterprise."

139. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

140. At all relevant times, the Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

141. At all relevant times, the RICO Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)

functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

142. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion.

143. Members of the Pain Care Forum ("PCF") and the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

144. The RICO Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits

were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

145. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

146. Within the RICO Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis.

147. These interpersonal relationships also formed the organization of the RICO Enterprise. The RICO Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

148. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The Defendants participated in the operation and management of the RICO Enterprise by directing its affairs, as described herein.

149. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

150. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF, the HDA, and through their contractual relationships.

151. The PCF has been described as a coalition of drugmakers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

152. The Center for Public Integrity and the Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse." Specifically, PCF participants spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.

153. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF. In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson, Allergan, and Teva. Each Manufacturer Defendant worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.

154. The 2012 Meeting Schedule for the PCF is specific example of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were generally held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis. Local members were encouraged to attend the monthly meetings in person.

155. The 2012 PCF Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

156. Second, the HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants are members. And, the HDA and each of the Distributor Defendants sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

157. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections." The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

158. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants. The manufacturer membership application must be signed by a "senior company executive," and it requests that the

manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

159. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HAD and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.

d. Logistics Operation Committee: "This committee initiates projects

designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.

160. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

161. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues." The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry." The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

162. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.

163. These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and

chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, ship notices, acknowledgements, and invoices. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

164. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and anti-diversion duties.

165. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants was in communication and cooperation.

166. According to articles published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor Defendants for more than a decade. And, from 2006 to 2016 the Distributor and Manufacturer

Defendants worked together through the PCF to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.

167. As described above, the Defendants began working together as early as 2006 through the PCF and the HDA to promote the common purpose of their enterprise.

168. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

**Defendants' Conduct**

169. During the time period alleged in this Complaint, the Defendants exerted control over, conducted and/or participated in the RICO Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

170. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

171. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

172. Defendants paid nearly $800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. The Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

173. The Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

174. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids. Defendants lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

175. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. And the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

176. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Defendants.

177. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

178. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings.

179. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders—all for failure to report suspicious orders.

180. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

181. The Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

182. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the PCF;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

j. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA

k. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

**Pattern of Racketeering Activity**

183. The Defendants conducted and participated in the conduct of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. §1961(B), including mail fraud (18 U.S.C. §1341) and wire fraud (18 U.S.C. §1343); and 18 U.S.C. §1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

**Mail and Wire Fraud**

184. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Plaintiff and the Class, by knowingly conducting or participating in the conduct of the RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

185. The Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the RICO Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

186. The Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform

misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

187. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

188. The Defendants' predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

a. Mail Fraud: The Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

189. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third

parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and facilitated Defendants' DEA registrations;

e. Documents and communications that supported and facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. §827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. §823 and 21 C.F.R. §1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for

memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

190. The Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

191. Defendants and The Drugs They Manufacture:

| **Defendant Group Name** | **Company Names** | **Drugs** | | |
|---|---|---|---|---|
| | | **Drug Name** | **Chemical Name** | **CSA Schedule** |
| **Purdue** | **(1)** Purdue Pharma, LP, **(2)** Purdue Pharma, Inc., **(3)** The Purdue Frederick Company | OxyContin | Oxycodone hydrochloride extended release | Schedule II |
| | | MS Contin | Morphine sulfate extended release | Schedule II |
| | | Dilaudid | Hydromorphone hydrochloride | Schedule II |
| | | Dilaudid-HP | Hydromorphone hydrochloride | Schedule II |
| | | Butrans | Buprenorpine | Schedule III |
| | | Hysingla ER | Hydrocodone bitrate | Schedule II |
| | | Targiniq ER | Oxycodone hydrochloride and naloxone | Schedule II |
| **Cephalon** | **(1)** Cephalon, Inc., **(2)** Teva Pharmaceutical Industries, Ltd., **(3)** Teva Pharmaceuticals USA, Inc. | Actiq | Fentanyl citrate | Schedule II |
| | | Fentora | Fentanyl citrate | Schedule II |
| | | Generic Oxycontin | Oxycodone hydrochloride | Schedule II |

| | | | | |
|---|---|---|---|---|
| **Janssen** | **(1)** Johnson & Johnson; **(2)** Janssen Pharmaceuticals, Inc. (*formerly* **(2a)** *Ortho-McNeil-Janssen Pharmaceuticals, Inc., formerly* **(2b)** *Janssen Pharmaceutica, Inc.* Also, Johnson & Johnson owns >10% of Janssen Pharmaceuticals Stock and controls the sale and development of drugs and its profits inure to Johnson & Johnson's benefit); **(3)** Noramco, Inc. (*wholly owned subsidiary of Johnson & Johnson*). | Duragesic | Fentanyl | Schedule II |
| | | Nucynta [Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015] | Tapentadol | Schedule II |
| | | Nucynta ER | Tapentadol extended release | Schedule II |
| **Endo** | **(1)** Endo Health Solutions Inc., **(2)** Endo Pharmaceuticals Inc., **(3)** Qualitest Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*) | Opana ER | Oxymorphone hydrochloride extended release | Schedule II |
| | | Opana | Oxymorphone hydrochloride | Schedule II |
| | | Percodan | Oxymorphone hydrochloride and aspirin | Schedule II |
| | | Percocet | Oxymorphone hydrochloride and acetaminophen | Schedule II |
| | | Generic oxycodone | | Schedule II |
| | | Generic oxymorphone | | Schedule II |
| | | Generic hydromorphone | | Schedule II |
| | | Generic hydrocodone | | Schedule II |
| **Mallinckrodt** | **(1)** Mallinckrodt PLC; **(2)** Mallinckrodt, LLC (*wholly-owned subsidiary of Mallinckrodt PLC*) | Exalgo | Hydromorphone hydrochloride | Schedule II |
| | | Roxicodone | Oxycodone hydrocloride | Schedule II |

| | | | | |
|---|---|---|---|---|
| **Allergan** | **(1)** Allergan Plc,<br>**(2)** Actavis LLC,<br>**(3)** Actavis Pharma, Inc.,<br>**(4)** Actavis Plc,<br>**(5)** Actavis, Inc.,<br>**(6)** Watson Pharmaceuticals, Inc.,<br>**(7)** Watson Laboratories, Inc.,<br>**(8)** Watson Pharma, Inc. | Kadian | Morphine sulfate | Schedule II |
| | | Norco (Generic of Kadian) | Hydrocodone and acetaminophen | Schedule II |
| | | Generic Duragesic | Fentanyl | Schedule II |
| | | Generic Opana | Oxymorphone hydrochloride | Schedule II |
| **Insys** | Insys Therapeudics, Inc. | Subsys | Fentanyl | Schedule II |

192. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

193. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

194. Defendants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

195. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

196. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of

Health and Human Services, that required the Defendants annually to certify in writing that the Defendants had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion RICO Enterprise's operation and goals, including false and misleading certifications required annually under the following:

a. Section V. of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014)

b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);

c. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and

d. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

197. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme

and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

198. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

199. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. §1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

200. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

201. The Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

202. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

203. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

204. The Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

205. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to their business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the RICO Enterprise and in furtherance of its fraudulent scheme.

206. The pattern of racketeering activity and the RICO Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the RICO Enterprise.

207. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

208. Many of the precise dates of the Defendants' criminal actions have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the RICO Enterprise alleged herein depended upon secrecy.

209. Each instance of racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting

similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the RICO Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiffs, or the community. In designing and implementing the scheme, at all times Defendants knew that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

210. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

211. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

212. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

213. The Defendants conducted and participated in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

214. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

215. Each of the Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

216. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

217. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

218. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015,

McKesson filed a Form 8K with the SEC announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

219. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring." Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."

220. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that

Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.

221. These examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. §1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California and Denver, Colorado;

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken

against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

222. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

223. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court. Many of the precise dates of Defendants' unlawful actions were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the RICO Enterprise depended upon the secrecy of the participants in that enterprise.

224. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff, its insureds, and its community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from

unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

225. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

226. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

227. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

**RICO Damages**

228. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's and the Class' injuries in their business and property because Plaintiff and the Class paid for costs associated with the opioid epidemic. These harms are on-going.

229. Plaintiff's and the Class's injuries, were, and are being, proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiff would not have paid the health services and expenditures required as a result of the plague of drug-addicted insureds.

230. Plaintiff and the Class have injuries that were directly caused by the Defendants' racketeering activities.

231. Plaintiff and the Class were most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

232. Plaintiff and the Class seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

## SECOND CLAIM FOR RELIEF
## RICO Conspiracy – 18 U.S.C. § 1962(d)

233. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

234. Plaintiff brings this claim on its own behalf, and for others similarly situated, against all Defendants. At all relevant times, the Defendants were associated with the RICO Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity. Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

235. Defendants conspired to violate Section 1962(c), as alleged more fully in Count 1, by conducting the affairs of the RICO Enterprise through a pattern of racketeering activity, as incorporated by reference herein.

## PRAYER FOR RELIEF

WHEREFORE, DC 37, on behalf of itself and the Class, prays that the Court:

A. Grant class certification at an early practicable time to the Class described herein, and to any appropriate subclasses, under Rule 23(a) and Rule 23 (b)(1),(2), and/or (3), as applicable; appoint Plaintiff and its counsel to represent the class; appoint additional class or

subclass representatives as appropriate; and maintain this action as a class action for purposes of notice, trial, and resolution;

B. Enter judgment against Defendant and in favor of DC 37 and the Class;

C. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff and the Class for all damages; treble damages; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate;

D. Award DC 37 and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as the Court may deem just and proper under the circumstances.

**JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38, DC 37, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: December 12, 2017

*/s/ Philip S. Kushner*
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